DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

December 19, 2001

WARNING LETTER NO. 2002-NOL-17

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Ken Trinh, President
Jensen Tuna, Inc.
5885 Highway 311
Houma, Louisiana 70360

Dear Mr. Trinh:

We inspected your firm, located at 5885 Highway 311, Houma, Louisiana, on November 30 and December 6 - 7, 2001, and found that you have a serious deviation from the Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). This deviation causes your histamine forming fish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviation was as follows:

You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not monitor the temperature of the cooler at the packing and storage critical control points to control histamines as listed in your HACCP plan for histamine producing whole fresh fish.

We may take action without further notice if you do not promptly correct this violation. For instance, we may seize your product and/or enjoin your firm from operating.

We are aware that, during our inspection, you made a verbal commitment to correct violations observed at your firm. However, please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct this deviation and prevent its recurrence. You may wish to include in your response documentation such as copies of your cooler monitoring records or other useful information that would assist us in evaluating your correction. If you cannot complete this correction before you respond, we expect that you will explain the reason for your delay and state when you will correct the deviation.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483